

<b>TRANSMITTAL FORM</b>  (for all correspondence after initial filing)	Application #	08/981,665
	Confirmation #	8326
	Filing Date	November 5, 1997
	First Inventor	CIPKOWSKI
	Art Unit	1641
	Examiner	Grun, James Leslie
Total number of pages in this submission =	Docket #	P08948US01/BAS

ENCLOSURES (check all that apply)	
<input type="checkbox"/> Fees calculated below <input checked="" type="checkbox"/> Notice of Appeal to the U.S. Court of Appeals for the Federal Circuit <input type="checkbox"/> After Final Amendment/Reply <input type="checkbox"/> including Attachment(s) <input type="checkbox"/> Extension of Time Petition/Fee	<input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Drawing(s) <input type="checkbox"/> <input type="checkbox"/>

FEES CALCULATION: For claims if required and/or other fees as shown below:					
	NOW	Previously Paid For	Present Extra	Rate	\$
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TOTAL OF ABOVE CLAIMS FEES =					
<input type="checkbox"/> Reduction by 1/2 for small entity status of applicant					
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TOTAL OF ALL FEES =					0

- ☐ Payment of \$ is made by:
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- ☒ The Director is authorized to charge any fee, additional fee or extension fee due in connection herewith to Deposit Account No. 12-0555:
- (1) if no payment or an insufficient payment is enclosed and a fee is due in connection herewith; or
  - (2) If no petition for extension of time is enclosed but an EOT is required - and in this event, applicant hereby petitions under 37 CFR 1.136(a) for an extension of time of as many months as are required to render this submission timely.

Date: June 20, 2012

Signed By Douglas E. Schuman FOR #28,518  
Name: B. Aaron Schulman  
Attorney of Record Registration No.: 31,877

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## **IN THE U.S. PATENT AND TRADEMARK OFFICE**

U.S. Appl. No. 08/981,665

Confirmation No. 8326

Title: DEVICE FOR THE COLLECTION, TESTING, AND SHIPMENT OF  
BODY FLUID SAMPLES

Inventor(s): CIPKOWSKI, Stan

Filed: November 5, 1997

Art Unit: 1641

Examiner: Grun, James Leslie

Docket No. P08948US01/BAS

Customer No.: 000881

### **NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

Director, United States Patent and Trademark Office (USPTO)

Attention: Office of the Solicitor

600 Dulany Street

Madison West Building, Room 8C43

Alexandria, VA 22314

Sir:

Please take Notice that pursuant to 35 U.S.C. §§141 and 142, Applicant hereby  
appeals to the United States Court of Appeals for the Federal Circuit from the portion of  
the decisions of the USPTO Board of Patent Appeals and Interferences dated February 2,  
2012 and April 24, 2012, rejecting the claims of the above application under 35 U.S.C.  
§103(a).

Pursuant to 37 C.F.R. §1.301 and Federal Circuit Rule 15(a), three copies of this Notice of Appeal together with the fee prescribed by Federal Circuit Rule 52 (\$450) are being transmitted to the Clerk of the Court of Appeals for the Federal Circuit.

No other fee is believed to be due, but the Commissioner is hereby authorized to charge any fees that may be required by this paper to Deposit Account 12-0555.

Respectfully submitted,

*B. Aaron Schulman*  
#28,518

Date: June 20, 2012

By: B. Aaron Schulman  
Registration No.: 31,877

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,665	11/05/1997	STAN CIPKOWSKI	P08948US01/BAS	8326
881 7590 04/24/2012 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER GRUN, JAMES LESLIE	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 04/24/2012	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

iplaw@stites.com

08981 UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* STAN CIPKOWSKI

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Appeal 2011-007578  
Application 08/981,665  
Technology Center 1600

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Before DONALD E. ADAMS, LORA M. GREEN, and  
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellant has requested rehearing of the decision entered February 2, 2012 ("Decision"), which affirmed the rejections of claims 16, 18, and 19 (all of the pending claims) for obviousness. The request for rehearing is denied.

## DISCUSSION

Appellant argues that, as “previously pointed out, the primary reference cited in the Section 103 rejection, namely the May reference, discloses a device that is fundamentally different than Appellant’s claimed invention” (Req. Reh’g 1). Appellant asserts that the Board’s reliance on the language in May that the sample can be placed directly or indirectly on the test strip is misplaced, because in all of the embodiments of May, the front surface of the test strip is prevented from contacting the sample directly (*id.* at 2 (citing Decision, p. 9-10, FF11)).

These arguments are not persuasive. Here, May specifically teaches that a sample may be applied directly to the porous carrier, i.e., the test strip (Decision, pp. 9-10, FF11 (quoting May, p. 3)). Thus, even though all of the embodiments of May are drawn to an indirect application of the sample to the test strip, we do not agree with Appellant that the ordinary artisan would consider that a teaching away from direct application, even though that method of application may not be preferred by May. “[I]n a section 103 inquiry, ‘the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.’” *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976)). Thus, “[a]ll the disclosures in a reference must be evaluated, including nonpreferred embodiments, and a reference is not limited to the disclosure of specific working examples.” *In re Mills*, 470 F.2d 649, 651 (CCPA 1972) (citations omitted). In addition, like our appellate reviewing court, “[w]e will not read into a reference a

teaching away from a process where no such language exists.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006).

Moreover, Appellant’s argument, in essence, is that he disagrees with the Decision, but a request for rehearing must do more than re-argue issues that have already been decided, even if the applicant disagrees with the previous decision. A “request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board.” 37 C.F.R. § 41.52. An applicant dissatisfied with the outcome of a Board decision is entitled to appeal the decision, *see* 35 U.S.C. §§ 141 and 145, but is not entitled to have the same issue decided multiple times on the same record.

Since Appellant has not pointed out any points that we overlooked or misunderstood, we decline to revisit our earlier conclusions.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REHEARING DENIED

clj



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,665	11/05/1997	STAN CIPKOWSKI	3000	8326
<div>7590 02/02/2012 EDMUND M JASKIEWICZ 1730 M STREET NW SUITE 400 WASHINGTON, DC 20036</div>			<div>EXAMINER GRUN, JAMES-LESLIE</div>	
			<div>ART UNIT 1641</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 02/02/2012</div>	<div>DELIVERY MODE PAPER</div>

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The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* STAN CIPKOWSKI

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Appeal 2011-007578  
Application 08/981,665  
Technology Center 1600

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Before DONALD E. ADAMS, LORA M. GREEN, and  
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 16, 18, and 19. We have jurisdiction under 35 U.S.C. § 6(b).

## STATEMENT OF THE CASE

Claim 16 is the only independent claim on appeal, and reads as follows:

16. A drug of abuse immunoassay test card for testing a liquid test specimen in a container having an open top and comprising a thin flat member having a rectangular outline and having front and rear surfaces, said thin flat member having a longitudinal dimension extending between top and bottom ends defining a length and having a width less than said length, and being shaped to be insertable longitudinally into a container to contact a liquid test specimen therein,

one or more immunoassay test strips each having thereon immunoassay means to visually indicate presence or absence of a selected drug of abuse disposed longitudinally side-by-side in parallel within said thin flat member and enclosed between said front and rear surfaces,

each said one or more test strips having a bottom end defining a sample contacting portion and further having a test portion spaced longitudinally therefrom wherein, in use, the liquid test specimen moves by capillary action from the sample contacting portion to the test portion at which the presence or absence of the selected drug of abuse in the fluid sample is visually indicated,

the bottom end of each said one or more test strips being disposed at the bottom end of said thin flat member but spaced from the bottom end of said thin flat member, the top end of each said one or more test strips being spaced from the top end of said thin flat member,

said front surface of said thin flat member having a plurality of openings therein to register with and expose each of the sample contacting and test portions on the exposed surface of each of said one or more test strips exposed by said openings, including a sample contacting opening over said sample contacting portion of the test strip and a test opening over said test portion of said test strip,

said openings located so that the liquid test specimen initially travels through said sample contacting opening and contacts the exposed surface of the sample contacting portions of each of said one or more test strips exposed beneath said sample contacting openings and then moves by capillary action from the sample contacting portion of said one or more test strips to the test portion of said one or more test strips,

further comprising means within said thin flat member between said front and rear surfaces for defining one or more longitudinally extending slots to longitudinally dispose said one or more test strips, each said one or more slots having both ends closed and spaced from the respective top and bottom ends of said thin flat member, and said one or more immunoassay test strips each seated within a respective slot.

The following grounds of rejection are before us for review:

- I. Claims 16, 18, and 19 stand rejected under 35 U.S.C. § 112, first paragraph, as containing new matter.
- II. Claims 16, 18, and 19 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of May,<sup>1</sup> Sun,<sup>2</sup> and Boger.<sup>3</sup> As Appellant does not argue the claims separately, we focus our analysis on claim 16, and claims 18 and 19 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

We reverse Rejection I, but affirm Rejection II.

#### ISSUE (New Matter)

Does the preponderance of evidence of record support the Examiner's finding that independent claim 16 contains new matter?

#### FINDINGS OF FACT

FF1. The Specification teaches that the "present invention relates to a test kit for the collection and testing of urine samples for drug of abuse,"

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<sup>1</sup> May et al., WO 88/08534, published Nov. 3, 1988.

<sup>2</sup> Sun et al., US 5,238,652, issued Aug. 24, 1993.

<sup>3</sup> Boger et al., US 4,518,565, issued May 21, 1985.

wherein the test kit comprises “a test card for indicating visually the presence of particular drugs of abuse” (Spec. 1).

FF2. Figure 9 of the instant disclosure is reproduced below:

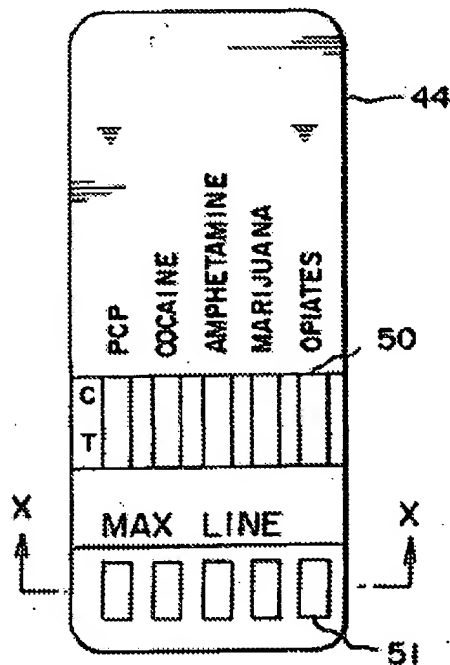


Figure 9 is a plan view of one embodiment of a test card disclosed in the Specification (*id.* at 7).

FF3. According to the Specification:

A modification of the test card is shown at 44 in Fig. 9. In this modification, the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings. The test card 44 comprises a central ply 45 [as can be seen in Figure 10, not reproduced] of styrene which has a thickness of 1.25 mm. corresponding to or slightly greater than the thickness of the test strips and slots are provided in the center ply to receive the test strips. . . . The top ply 47 is provided with a plurality of test windows 50 through which the test results as indicated by the test strips can be seen. At the lower end of the card are provided sample openings 51 through

which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.

(*Id.* at 11-12.)

FF4. The Examiner finds that the disclosure, as originally filed:

does not provide support for a sample **contacting** portion on **the exposed surface** (i.e., front) of the **test strip** so that liquid sample flows through the sample opening in the thin flat member strip holder and contacts the **exposed surface** (i.e., front) of the sample portion exposed beneath (i.e., registering with) the opening.

(Ans. 4.)

FF5. Specifically, according to the Examiner:

[A]ppellant merely discloses that specimen is able to contact the “absorbent or sample portions” of the test strips through the sample openings of the card (see e.g. page 12). There is no disclosure that these portions are necessarily on, or only on, the exposed surface of the test strip.

(*Id.* at 4-5.)

## ANALYSIS

Appellant argues that the claim language is not new matter, but is supported by Figure 9 and pages 11-12 on the instant Specification (App. Br. 7-8).

We conclude that Appellant has the better position.

The test for determining whether a specification is sufficient to support a particular claim “is whether the disclosure of the application relied upon ‘reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.’” *Ralston Purina Co. v. Far-*

*Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). Thus, “[i]t is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations.” *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976) (citation omitted); *see also Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (“In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.”).

The Specification teaches that “the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings” (FF3). The Specification teaches further that at “the lower end of the card are provided sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.” While there may be no specific disclosure that these portions are necessarily on, or only on, the exposed surface of the test strip, we conclude that the person of ordinary skill in the art would understand that Appellant reasonably had possession of a test card having a sample contacting portion on the exposed surface (i.e., front) of the test strip so that the liquid sample flows through the sample opening in the thin flat member strip holder and contacts the exposed surface (i.e., front) of the sample portion exposed beneath (i.e., registering with) the opening.

### CONCLUSION OF LAW

We conclude that the preponderance of evidence of record does not support the Examiner's finding that independent claim 16 contains new matter. We thus reverse the rejection of claims 16, 18, and 19 under 35 U.S.C. § 112, first paragraph, as containing new matter.

### ISSUE (Obviousness)

Does the preponderance of the evidence of record support the Examiner's conclusion that the combination of May, Sun, and Boger renders obvious the immunoassay card of claim 16?

### FINDINGS OF FACT

- FF6. We adopt the Examiner's findings and conclusions as our own.
- FF7. We also highlight the following teachings of May.
- FF8. Figures 11 and 12 of May are reproduced below:

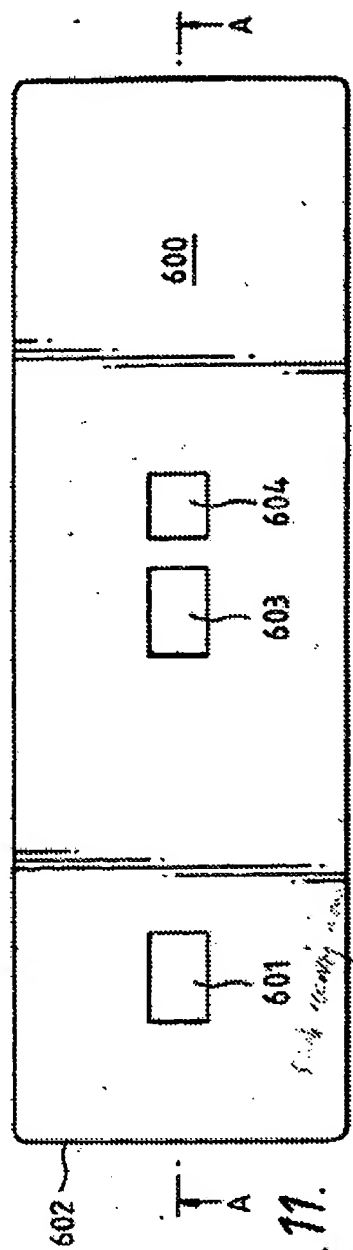


Fig. 11.

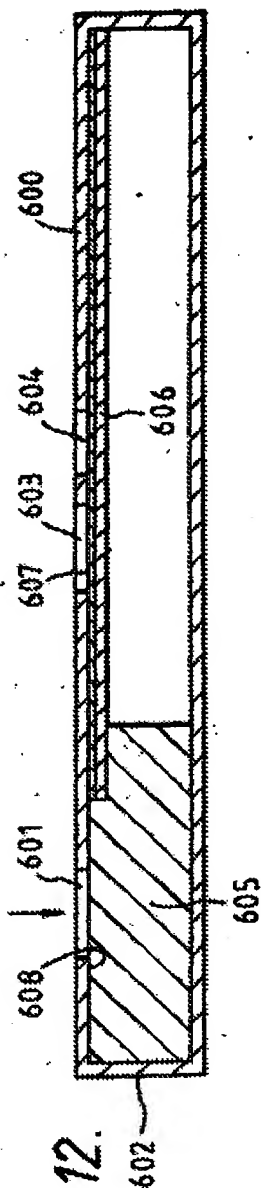


Fig. 12.



Figures 11 and 12 are drawn to the embodiment of the test strip of May: the plan view is shown in Figure 11 and the cross-sectional view is shown in Figure 12 (May p. 27).

FF9. The test strip contains an aperture 601, through which a sample may be applied (*id.* at 27-28).

FF10. As to the embodiment shown above, May teaches:

[T]he device is hollow and incorporates within it a porous sample receiving member adjacent end 602 of casing 600 and lying directly beneath aperture 601. A test strip . . . comprising a porous strip 606 backed by a transparent plastics sheet 607 is also contained within casing 600, and extends from the porous receiving member 602, with which the porous carrier is in liquid permeable contact, to the extreme other end of the casing. The transparent backing sheet 607 is in firm contact with the upper inner surface 608 of casing 600, and provides a seal against apertures 603 and 604 to prevent ingress of moisture or sample into the casing.

(*Id.* at 27.)

FF11. May teaches further:

A typical embodiment of the invention . . . an analytical test device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates *directly or indirectly* with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device also containing a labelled [sic] specific binding reagent for an analyte which labelled [sic] specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabelled [sic] specific binding reagent for the same analyte which unlabelled [sic] reagent is permanently immobilised [sic] in a detection zone on the carrier material and is therefore not mobile in the moist state, the relative positioning of the labelled [sic] reagent and detection zone being such that liquid sample applied to the

device can pick up labelled [sic] reagent and thereafter permeate into the detection zone, and the device incorporating means enabling the extent (if any) to which the labelled [sic] reagent becomes in the detection zone to be observed.

(*Id.* at 3 (emphasis added).)

### ANALYSIS

Appellant argues that none of the references relied upon by the Examiner “**disclose the specific test card of the present invention**, namely one wherein the test card houses one or more immunoassay strips wherein the liquid specimen passes through the opening directly above the sample contacting portion on the front of the test strip and then proceeds via capillary action along the strip to the test portion wherein an analyte in the specimen may be visually determined through another opening in the test card” (App. Br. 12).

Specifically, Appellant asserts that “the May reference **teaches away** from the present claims because the device disclosed therein **covers up** in all cases the front surface of the test strip and **prevents** the sample from contacting the test strip on the front surface of the test strip” (*id.*; *see also* Reply Br. 9). Appellant points to Figures 11 and 12, wherein “the fluid sample is contacted only through the end of the test strip 606 which is blocked from receiving a fluid sample on the front end of the test strip” (*id.* at 12-13). Appellant further asserts that neither Sun nor Boger remedy that deficiency of May (*id.* at 13).

Appellant’s arguments have been carefully considered, but are not convincing. As can be seen from Figures 11 and 12 of May, May teaches a

test case having a test strip therein, wherein the case has an opening therein exposing a sample receiving member directly beneath the opening 601 (FF9). While in the embodiment shown in Figures 11 and 12, the sample is not directly applied to the test strip, but is instead applied to a sample receiving member, May specifically teaches that the dry porous carrier that makes up the test strip may communicate with the exterior of the casing either directly or indirectly with the exterior of the casing so that the test sample may be applied (*see* FF11; *see also* Ans. 8, 21). Thus, we agree with the Examiner (*see, e.g.*, Ans. 21) that it would have been well within the level of skill of the ordinary artisan to position a sample receiving portion of the test strip of May underneath the aperture 601 in order to apply the sample directly to the test strip.

#### CONCLUSION OF LAW

We conclude that the preponderance of the evidence of record supports the Examiner's conclusion that the combination of May, Sun, and Boger renders obvious the immunoassay card of claim 16. We thus affirm the rejection of claim 16 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of May, Sun, and Boger. As claims 18 and 19 stand or fall with claim 16, we affirm the rejection as to those claims as well.

Appeal 2011-007578  
Application 08/981,665

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc